6741.US.01

AMENDMENT

In response to the Office Action (Paper No. 8) dated January 4, 2005, reconsideration of the subject application and allowance thereof is respectfully requested in view of the amendment to the claims and specification as set forth below.

IN THE CLAIMS:

1. (Currently Amended) A method of determining the *initial dose* of a *vitamin D compound*[,] for the treatment of secondary hyperparathyroidism and renal osteodystrophy without increasing the incidence of hypercalcemia comprising:

a. measuring a patient *baseline PTH* (bPTH) value,

b. determining [the] a *final dose* of the vitamin D compound, where the final dose is that dose associated with a first stable clinically significant reduction in patient intact parathyroid hormone (PTH) for the vitamin D compound,

c. applying the *baseline PTH* value and *final dose* to regression analysis, and

d. calculating the *initial dose* of the *vitamin D compound* from the regression analysis of step c.

2. (Currently Amended) The method of claim 1 wherein the [linear model] regression analysis is a zero intercept linear model.

3. (Original) The method of claim 1 wherein the vitamin D compound is a vitamin D_2 compound.

4. (Original) The method of claim 3 wherein the vitamin D_2 compound is paricalcitol.

5. (Currently Amended) The method of claim 4 wherein the initial dose is patient baseline PTH/80 (bPTH/80).

6. (Currently Amended) [The] A method of treating secondary hyperparathyroidism and renal dystrophy using a vitamin D compound without increasing the incidence of hypercalcemia [claim 1 further] comprising

a) measuring a patient baseline PTH value;

b) determining a final dose of the vitamin D compound associated with a first stable clinically significant reduction in patient PTH for the vitamin D compound;

c) applying the baseline PTH and final dose to regression analysis;

d) calculating the initial dose of the vitamin D compound from the regression analysis of step c; and

e) [administration of] administering the initial dose determined in step d to the patient.

7. (Currently Amended) A method of treating elevated intact parathyroid hormone (PTH) in a patient commencing treatment for [ESRD] end stage renal disease, the method comprising:

a. determining the initial dose of a vitamin D compound from a regression analysis based on a patient baseline PTH (bPTH) and a final dose of the vitamin D compound associated with a first stable and clinically significant reduction in patient PTH for the vitamin D compound, and

b. administering the initial dose of the vitamin D compound determined in step a to the patient.

8. (Original) The method of claim 7 wherein the vitamin D compound is paricalcitol.

9. (Currently Amended) The method of claim 8 wherein the initial dose is about patient baseline parathyroid hormone/80 (bPTH/80).

10. (Currently Amended) A method of treating a patient [undergoing vitamin D therapy] for end stage renal disease [ESRD] using a vitamin D therapy, [wherein the] comprising administering an initial dose of vitamin D [administered] to the patient wherein the initial dose of vitamin D is about patient baseline parathyroid hormone/80 (bPTH/80) and bPTH is the baseline PTH for the patient.

11. (Currently Amended) A method of treating a patient [undergoing vitamin D therapy] for secondary hyperparathyroidism using a vitamin D therapy, [wherein the] comprising administering an initial dose of vitamin D [administered] to the patient wherein the initial dose of vitamin D is about patient baseline parathyroid hormone/80 (bPTH/80) and bPTH is the baseline PTH for the patient.

12. (Currently Amended) A method of determining the initial dose of a vitamin D compound using a zero-intercept linear regression model [to determine the initial dose of a vitamin D compound].

13. (Currently Amended) A method of treating a patient undergoing vitamin D therapy for [ESRD] end stage renal disease wherein a zero-intercept regression model is used to determine the initial dose of the vitamin D compound.

14. (Currently Amended) The method of claim 13, wherein the vitamin D therapy [the vitamin D compound] results in the prevention or treatment of renal osteodystrophy or secondary hyperparathyroidism.

15. (Original) A method of claim 8 wherein the initial dose is at least 1 mcg.

16. (New) The method of claim 13, wherein the vitamin D therapy does not increase the incidence of hypercalcemia.